MRI Safety
And
Implanted Medical Devices

Presented By:

Tobias Gilk, M.Arch, HSDQ

President & MRI Safety Director, Mednovus, Inc.

Sr. Vice President, RAD-Planning

Tobias Gilk, M.Arch, HSDQ

- **Former Member, ACR MR Safety Committee and co-author of the *ACR Guidance Document for Safe MR Practices: 2007.***
- **Recipient American Institute of Architects 'Best Practices' Citation for MRI Safety design work.**
- **Author American Society of Healthcare Engineering monograph, *Designing and Engineering MRI Safety.***
- **Special contributing author US Department of Veteran Affairs, *MRI Design Guide.***
- **Member of Patient Safety Working Group for Facilities Guidelines Institute committee for the 2010 edition of *Guidelines for Design and Construction of Health Care Facilities*.**
- **Contributor to 2010 edition of *Guidelines for Design and Construction of Health Care Facilities*.**
- **Member of Imaging Task Group for Facilities Guidelines Institute committee for the 2014 edition of *Guidelines for Design and Construction of Health Care Facilities*.**
- **Former member of IEC TAG on radiology safety.**
- **Invited international presenter / lecturer on MRI suite design and safety.**
- **Volunteer surveyor trainer for MRI Safety for The Joint Commission.**
- **Author of 100's of articles on MRI safety.**

MRI Implant Safety Begins Before Implantation

When roughly 10% of the US population gets MRI annually, it's inconceivable manufacturers can market new implants without any MRI safety statements!

Manufacturers of implants must include statements of MRI safety, even if only:

"*This device not tested for MRI Safety*"

MRI Implant Safety Continues At Implantation

All implants, whether active or passive, should include a product data card. The implant information must be entered into the patient's medical record, and the patient must be directly provided with this information.

MRI Implant Safety Continues At Implantation

If the information is not directly conveyed to the patient (and medical record), then the procedure is not complete.

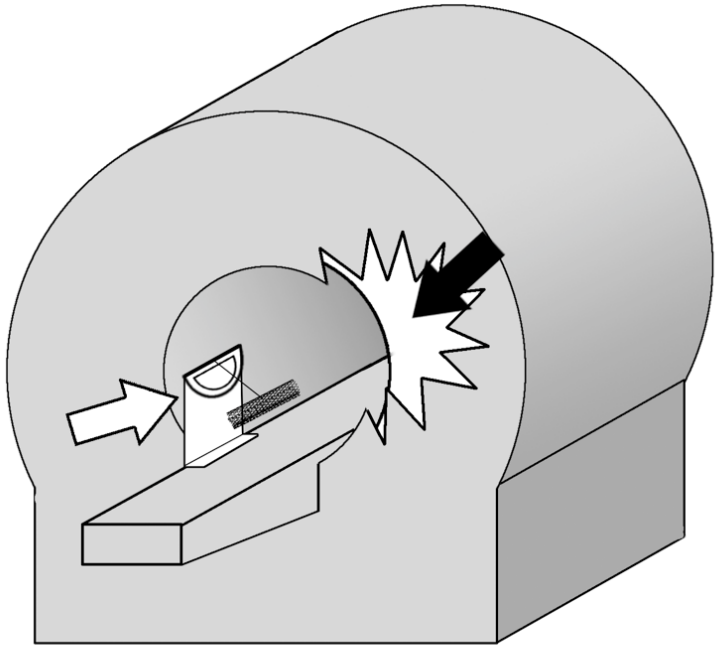
And if the procedure is not complete, *should it be reimbursed*?

MRI Implant Safety
At Point-of-Care

Without product labeling and recorded information for implants, it becomes difficult (and often impossible) to determine the risks for an individual patient.

MRI Implant Safety
At Point-of-Care

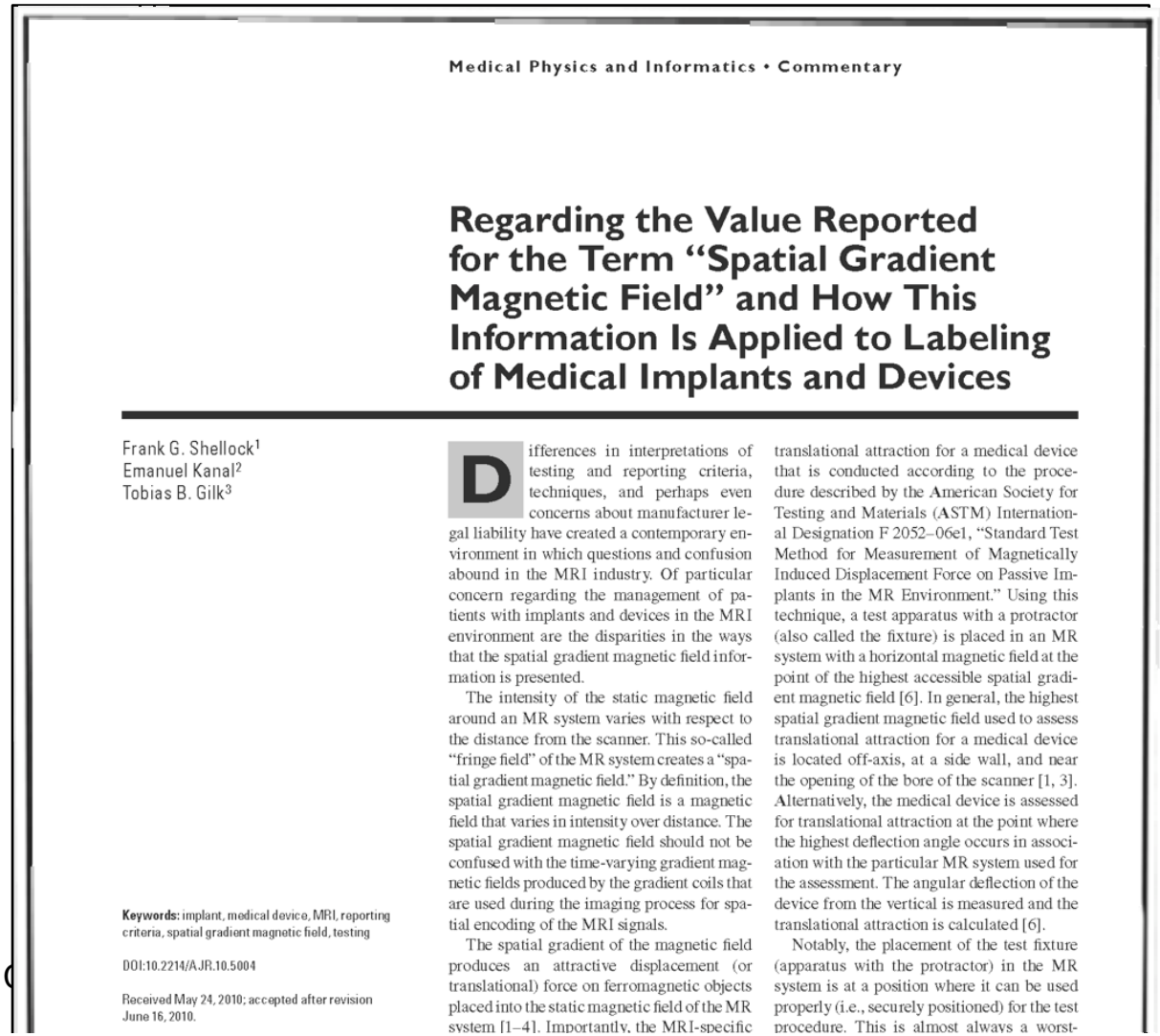
Even *with* implant information, often risk assessments are made difficult by insufficient information about the MRI scanner.



MRI Implant Safety
At Point-of-Care

Current implant testing methods, coupled with limited disclosures from MR system manufacturers, inform MRI providers that implants are unsafe when scanned on the exact same MRI system used to prove their MR Conditional safety!

MRI Implant Safety At Point-of-Care



Regarding the Value Reported for the Term "Spatial Gradient Magnetic Field" and How This Information Is Applied to Labeling of Medical Implants and Devices

Frank G. Shellock[1]
Emanuel Kanal[2]
Tobias B. Gilk[3]

Differences in interpretations of testing and reporting criteria, techniques, and perhaps even concerns about manufacturer legal liability have created a contemporary environment in which questions and confusion abound in the MRI industry. Of particular concern regarding the management of patients with implants and devices in the MRI environment are the disparities in the ways that the spatial gradient magnetic field information is presented.

The intensity of the static magnetic field around an MR system varies with respect to the distance from the scanner. This so-called "fringe field" of the MR system creates a "spatial gradient magnetic field." By definition, the spatial gradient magnetic field is a magnetic field that varies in intensity over distance. The spatial gradient magnetic field should not be confused with the time-varying gradient magnetic fields produced by the gradient coils that are used during the imaging process for spatial encoding of the MRI signals.

The spatial gradient of the magnetic field produces an attractive displacement (or translational) force on ferromagnetic objects placed into the static magnetic field of the MR system [1–4]. Importantly, the MRI-specific translational attraction for a medical device that is conducted according to the procedure described by the American Society for Testing and Materials (ASTM) International Designation F 2052–06e1, "Standard Test Method for Measurement of Magnetically Induced Displacement Force on Passive Implants in the MR Environment." Using this technique, a test apparatus with a protractor (also called the fixture) is placed in an MR system with a horizontal magnetic field at the point of the highest accessible spatial gradient magnetic field [6]. In general, the highest spatial gradient magnetic field used to assess translational attraction for a medical device is located off-axis, at a side wall, and near the opening of the bore of the scanner [1, 3]. Alternatively, the medical device is assessed for translational attraction at the point where the highest deflection angle occurs in association with the particular MR system used for the assessment. The angular deflection of the device from the vertical is measured and the translational attraction is calculated [6].

Notably, the placement of the test fixture (apparatus with the protractor) in the MR system is at a position where it can be used properly (i.e., securely positioned) for the test procedure. This is almost always a worst-

Keywords: implant, medical device, MRI, reporting criteria, spatial gradient magnetic field, testing

DOI:10.2214/AJR.10.5004

Received May 24, 2010; accepted after revision June 16, 2010.

MRI Implant Safety
At Point-of-Care

In order for MRI providers to evaluate MRI safety of implants and devices, they must have information about the spatial distribution of the MRI's magnetic field!

Please require all MRI manufacturers to provide MSG and FP maps for scanners.

MRI Implant Safety Steps

1. Require MRI safety statements for all newly approved implants & devices.

2. Require complete implant information in the medical record *and* provided directly to patient.

3. Require MSG / FP maps from MR system manufacturers.

4. Require regular MRI safety training for MR personnel.

Thank You!